K003677

DEC 2 6 2000

DIAGNOSTICS

Premarket Notification [510(k)] Summary

Company: ABX Diagnostics, Inc.
34 Bunsen Drive
Irvine, CA 92618
Phone: (949) 453-0500
Fax: (949) 453-0600
Contact Person: Bruce Davis
Date Prepared: October 27, 2000

Trade Name: **ABX PENTRA 60C+ Hematology Analyzer**

Common Name: Automated cell counter and
Automated differential cell counter

Classification Name: Automated cell counter (864.5200) and
Automated differential cell counter (864.5220)

Substantial Equivalence:

The **ABX PENTRA 60C+ Hematology Analyzer** is substantially equivalent to the PENTRA 60 Hematology Analyzer (K992511, cleared to market October 15, 1999).

Description:

The **ABX PENTRA 60C+ Hematology Analyzer** is a benchtop, clinical laboratory instrument which analyzes *in-vitro* samples of whole blood to provide complete blood count and leucocyte differential count using principles of cytochemistry, focused flow impedance and light transmission using a halogen light source. The instrument is microprocessor driven and connected to a PC that performs further data processing and hosts the user interface.

Indications for Use:

The **ABX PENTRA 60C+ Hematology Analyzer** is a fully automated (microprocessor controlled) hematology analyzer used for the *in vitro* diagnostic testing of whole blood specimens.

The **ABX PENTRA 60C+** is able to operate either in complete blood count (CBC) mode or in CBC + 5 differential leucocyte count (5DIFF) mode.

Comparison to Predicate Devices:

The **ABX PENTRA 60C+ Hematology Analyzer** is substantially equivalent to the already cleared device with respect to the indications for use, the hematological parameters for complete blood count and differential leucocyte count, and the principles of operation. It is different with respect to those modifications in hardware (mechanical and pneumatic) necessary to add a closed-tube module. Also, the graphic user interface and part of data processing are handled via an added PC workstation.

Discussion of Verification and Validation Activities:

The determination of substantial equivalence was based verification and validation activities that are part of the ABX design control system. Verification activities included within-run, between-run and between-day precision studies, assay linearity studies and sample carryover studies. Additionally interprocedural correlation studies were conducted using human blood samples processed in the **ABX PENTRA 60C+ Hematology Analyzer** and in the PENTRA 60 Hematology Analyzer. Validation activities included software validation.

Conclusions:

Verification and validation activities indicate that the **ABX PENTRA 60C+** is substantially equivalent to the predicate device.

Prepared By: Pat Amtower
Consultant, ProMedica International

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 6 2000

Bruce H. Davis, M.D.
Director of Medical Affairs
ABX Diagnostics, Inc.
34 Bunsen Drive
Irvine, California 92618

Re: K003677
Trade Name: ABX PENTRA 60C+ Hematology Analyzer
Regulatory Class: II
Product Code: GKZ
Dated: November 24, 2000
Received: November 29, 2000

Dear Dr. Davis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003677

Device Name: **ABX PENTRA 60C+ Hematology Analyzer**

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(PLEASE DO NOT WRITE BELOW ~~THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED~~)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CRFR 801.109)

Peter E. Maglione

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003677